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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,135	03/04/2002	Te Piao King	2313/1H587-US1	5158

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,135

Applicant(s)

KING ET AL.

Examiner

Patrick J. Nolan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1-4 and 7-19 are pending.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4 and 7-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptide epitope sequence that is at least 10 amino acids in length, does not reasonably provide enablement for a peptide epitope sequence that is less than 10 amino acids in length. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments filed 7-1-05 have been fully considered but are not found persuasive.

Applicant argues they have a working example demonstrating that a 10mer worked and that the claimed may have inoperable embodiments and still be enabled.

However, the specification has no working demonstrating a peptide less than 10 amino acids is effective in eliciting a protective IgG immune response. The state of the Art casts doubt on the use of scaffolding for IgG production from allergens and there is evidence in Applicant's specification that an 8-mer did not induce a protective IgG response. The combined teachings of the 8-mer example in the specification and the state of the art reference would lead one of ordinary skill in the immunological arts to believe it would be unpredictable to practice the full scope of the claimed invention.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-4 and 10-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Monsalve et al., (Reference 1 on the IDS submitted 10-15-03) or Monsalve et al., (Reference 7 on the IDS submitted 10-15-03) as evidenced by King et al. (Reference 3, on the IDS submitted 10-15-03), all of record for reasons set forth in the Office Action mailed 2-1-05.

Applicant arguments filed 7-1-05 have been fully considered but are not found persuasive.

Applicant argues that about 45 does not read upon an amino acid sequence of 49 amino acids.

However, it is noted that claim 17 which depends upon claim 13, which depends upon claim 12, which depends upon claim 1, encompasses a peptide epitope that is 49 amino acids in length, it also recites a peptide epitope that is 95 amino acids in length. Since a dependent claim must encompass all the limitations of the claims from which it depends, the term about 45 easily reads upon a 49-mer, as well as a 95-mer peptide epitope.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monsalve et al., (Reference 1 on the IDS submitted 10-15-03) or Monsalve et al., (Reference 7 on the IDS submitted 10-15-03) as evidenced by King et al. (Reference 3, on the IDS submitted 10-15-03) in view of US Patent 6,639,054 B1, all of record for reasons set forth in the Paper mailed 2-1-05.

It is noted the '054 recognizes that conservative substitutions to IgE epitopes will reduce the IgE antibody binding ability of the resulting conservative substituted epitope.

Applicant's arguments filed 7-01-05 have been fully considered but are not found persuasive.

Applicant's argues there is no motivation to combine the '054 teachings with the Monsalve et al., references.

However, Monsalve et al., clearly recognizes the desire to create a peptide epitope that has reduced IgE binding. The '054 teaches one recognized way of doing that.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

September 13, 2005


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

9/13/05